

DISPOSITION: Mrs. Yuba G. Freeman filed a plea of intervention and, thereafter, the Government filed interrogatories, which were answered by the intervenor. The Government then filed a motion for summary judgment based on the answers to interrogatories. On 2-24-62, the court entered an order granting the motion for summary judgment, condemning the article, and providing for delivery of the device to the Food and Drug Administration.

DRUG FOR VETERINARY USE

7030. Turkey Formula Streppenmycin. (F.D.C. No. 46156. S. No. 54-595 R.)

QUANTITY: 1 keg containing 18 unlabeled 5-lb. bags at Lone Rock, Wis.

SHIPPED: 5-24-61, from Mankato, Minn., by Paul's Products Co.

LABEL IN PART: (Keg) "Turkey Formula 100 pounds 20/5# bags * * * Streppenmycin * * * As an aid in the control of Streptomycin and Penicillin sensitive bacteria usually present in infectious sinusitis, air sac, or blue comb disease in turkeys. Each pound contains * * * manufactured by Paul's Products Co. Mankato, Minnesota Directions * * * Control No. 213 Exp. Date Sep. 1963."

LIBELED: 8-2-61, W. Dist. Wis.

CHARGE: 502(b)—when shipped and while held for sale, the article failed to bear a label (bag) containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of quantity of contents; 502(e) (2)—its label failed to bear the common or usual name of each active ingredient; and 502(f) (1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 3-17-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7031. Calcium lactate tablets. (F.D.C. No. 47224. S. No. 24-407 T.)

QUANTITY: 4 25,000-tablet drums and 1 20,000-tablet drum at Cleveland, Ohio.

SHIPPED: 12-6-61, from Worcester, Mass.

RESULTS OF INVESTIGATION: Examination showed the presence of moldy tablets.

LIBELED: 3-8-62, N. Dist. Ohio.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as *calcium lactate tablets*, a drug, the name of which is recognized in the National Formulary, an official compendium, and its quality or purity fell below the standard set forth in such compendium by reason of the presence therein of moldy tablets.

DISPOSITION: 4-25-62. Default—destruction.

7032. Trisulfacidin suspension. (F.D.C. No. 47172. S. No. 38-556 T.)

QUANTITY: 8 1-gal. btls. at Birmingham, Ala.

SHIPPED: 11-17-61, from St. Louis, Mo., by Organo Pharmaceutical Co.

LABEL IN PART: (Btl.) "Cyclonized Trisulfacidin Suspension * * * Each Teaspoon (5 cc.) contains: Sulfadiazine 0.166 Gm. Sulfamerazine 0.166 Gm. Sulfamethazine 0.166 Gm. Pyrilamine Maleate 6.25 mg. Pheniramine Male-

*See also No. 7005.

ate 6.25 mg. Phenylpropanolamine HCl 12.5 mg., Sodium Citrate 250 mg. Jamieson-McKames Pharmaceuticals, Inc. St. Louis 16, Mo."

RESULTS OF INVESTIGATION: Analysis showed that the article contained sulfacetamide and not sulfamethazine.

LIBELED: 2-23-62, N. Dist. Ala.

CHARGE: 501(d)(2)—when shipped, sulfacetamide had been substituted in whole or in part for sulfamethazine; and 502(a)—the label statement "Sulfamethazine 0.166 Gm." was false and misleading as applied to a product which did not contain sulfamethazine.

DISPOSITION: 3-26-62. Default—destruction.

7033. Adhesive bandages. (F.D.C. No. 45353. S. Nos. 46-231/33 R.)

QUANTITY: 2 cases, containing 720 individually wrapped bandages in pkgs. of 10 each, and 1 case, containing 720 individually wrapped bandages in pkgs. of 12 each, at Lancaster, S.C.

SHIPPED: 10-6-60, from New Rochelle, N.Y., by Hampton Manufacturing Co.

LABEL IN PART: (Pkg.) "Blue Cross Plastic Adhesive Bandages Sterile * * * Hampton Mfg. Co. New Rochelle, N.Y. Plain Pads"; "Waterproof Blue Cross Sterile Adhesive Bandages Hampton Mfg. Co. New Rochelle, N.Y. * * * 'Mercurochrome' Pads H. W. & D. Brand of Merbromin"; and "Blue Cross Plastic Adhesive Bandages Sterile * * * Hampton Mfg. Co. New Rochelle, N.Y. 'Mercurochrome' Pads H. W. & D. Brand of Merbromin."

LIBELED: On or about 1-30-61, W. Dist. S.C.

CHARGE: 501(b)—the quality and purity of the article, when shipped, fell below the standard for adhesive absorbent bandage (adhesive absorbent compress) set forth in the United States Pharmacopeia since the article was not sterile but was contaminated with living microorganisms; and 502(a)—the label statement "Sterile" was false and misleading.

DISPOSITION: 4-17-62. Default—destruction.

7034. Rubber prophylactics. (F.D.C. No. 47058. S. No. 34-691 T.)

QUANTITY: 15 gross cases of individually foil-wrapped prophylactics, packed in boxes of 3, at St. Paul, Minn.

SHIPPED: 1-8-62 and 2-5-62, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Case) "One Gross 3's No. 10 In Foil Peacocks Redi-Wet * * * Dean Rubber Mfg. Co., North Kansas City, Missouri" and (box of 3) "3 Peacocks Redi-Wet Rubbers in Foil * * * An Aid in Preventing Venereal Disease."

RESULTS OF INVESTIGATION: Examination showed 4.74 percent of the article was defective in that it contained holes.

LIBELED: 2-27-62, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 3-13-62. Consent—claimed by Dean Rubber Manufacturing Co. and destroyed.